

PATENT  
454313-2340.2REMARKS

Reconsideration and withdrawal of the rejections of the application and consideration and entry of this paper are respectfully requested in view of the amendments and remarks herewith, which place the application into condition for allowance.

I. STATUS OF CLAIMS AND FORMAL MATTERS

Claims 1, 2, 17-19, 21, 23-25, 31, 32, 43-50, 52, 54, 55, 62 and 63 are under examination in this application. Claims 1, 2, 17, 21, 24, 25, 43, 47, 50, 54, 55, 62 and 63 are amended without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents. Claims 26-28, 51, 53 and 56-60 are cancelled without prejudice, without admission, without surrender of subject matter, and without any intention of creating any estoppel as to equivalents.

No new matter has been added by these amendments. Support for the recitation of PCV-2 ORF1 and ORF2 can be found in the paragraph bridging pages 22 and 23 of the specification. These designations are used by Meehan et al., and correspond respectively with ORF4 and ORF13, claimed in original claim 28.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. §112. The amendments of and additions to the claims, as presented herein, are not made for purposes of patentability within the meaning of 35 U.S.C. §§§§ 101, 102, 103 or 112. Rather, these amendments and additions are made simply for clarification and to round out the scope of protection to which Applicants are entitled. Support is found throughout the specification and from the pending and originally filed claims. Further, changes to the claims herein are not narrowing amendments. Accordingly, no estoppel as to equivalents arises from or is intended by this paper.

II. INFORMATION DISCLOSURE STATEMENT

The Advisory Action indicated that the references submitted with paper no. 16 were not considered because they were not accompanied by the proper fee under 37 CFR 1.17(p) and a statement required under 37 CFR 1.97(e). The Commissioner is authorized to charge any requisite fee for consideration and entry of the U.S. Patent documents cited in the previous Amendment After Final to Deposit Account No. 50-0320. With regard to the statement, although the items were known to the Examiner, the Applicants' assignee and the undersigned,

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*inter alia*, more than three months prior to filing the IDS (for instance, as they are cited or correspond to citations in the application), in view of the amendments to the claims, as discussed and agreed upon with the Examiner, it is believed timely that the Examiner consider and make of record the previously-cited U.S. patents.

Therefore, the Examiner is respectfully requested to formally make of record U.S. Patent Nos. 6,391,314, 6,368,601, 6,207,165 and 6,217,883. PTO Form 1449, listing these patents, was attached to paper no. 16. The undersigned will gladly supply a copy of these patents in paper or electronic format (although it is believed that the Examiner has access to these patents).

### **III. THE REJECTIONS UNDER 35 U.S.C. § 112, 2<sup>ND</sup> PARAGRAPH, ARE OVERCOME**

Claims 1, 2, 17-19, 21, 23-28, 31, 32, 43-60, 62 and 63 were rejected 35 U.S.C. § 112, second paragraph, as allegedly being indefinite. The rejection is traversed.

The Advisory Action maintains that "it remains unclear which of the 13 PCV-2 polypeptides would be considered antigenic." The claims have been amended to recite a composition for reducing viral load, rather than for eliciting an immune response. Further, the claims now recite two specific polypeptides - PCV-2 ORF1 and PCV-2 ORF2, as designated by Meehan et al. Data presented in international publication WO 00/77216 demonstrates that canarypox vectors containing PCV-2 ORF1 and/or ORF2 are efficacious in reducing PCV-2 viral load in immunized piglets (see Example 9). Data presented in international publication WO 00/77188 demonstrates reduction of viral load by DNA plasmid immunogenic compositions that express PCV-2 ORF1, PCV-2 ORF2, or PCV-2 ORF1 and ORF2 (see Examples 8-10).

Therefore, it is clear that the two claimed PCV-2 polypeptides are antigenic and that the claims are definite. Reconsideration and withdrawal of the Section 112, second paragraph, rejections are requested.

### **IV. THE REJECTIONS UNDER 35 U.S.C. § 112, 1<sup>ST</sup> PARAGRAPH, ARE OVERCOME**

Claims 1, 2, 7, 17-19, 21, 23-28, 31, 32, 37, 43-60, 62 and 63 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement. The rejection is traversed.

It is argued in the Advisory Action that there is insufficient support for lowering viral titer with a vector encoding a PCV-2 polypeptide. As discussed above, there is support in the PCT applications WO 00/77216 (Example 9) and WO 00/77188 (Examples 8-10) for reducing viral load of PCV-2 by administering compositions comprising the claimed PCV-2 polypeptides. These applications correspond respectively to USSN 09/583,545 (allowed), claiming priority to

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USSN 60/138,478, and USSN 09/586,535, claiming priority to USSN 60/138,352, all of which are incorporated into this application by reference.

It is respectfully submitted that adequate guidance is provided to enable the skilled artisan to practice the claimed invention without undue experimentation. Therefore, reconsideration and withdrawal of the U.S.C. § 112, first paragraph rejections are earnestly solicited.

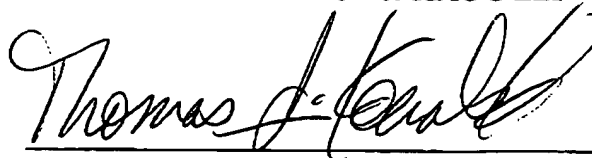
### CONCLUSION

In view of the remarks and amendments herewith and the matters previously discussed with the Examiner, the application is believed to be in condition for allowance. Consideration and entry of this paper, consideration and making of record the patents mentioned herein, favorable reconsideration of the application and reconsideration and withdrawal of the objections to and/or rejections of the application, and prompt issuance of a Notice of Allowance are earnestly solicited. It should be noted that no new issues have been raised by this Amendment, and thus, no further search is required by consideration and entry of this paper. Rather, the herewith amendments and arguments provide additional support for Applicants' position and previous arguments.

The undersigned looks forward to hearing favorably from the Examiner at an early date. If any issue remains as an impediment to allowance, a further interview is respectfully requested, with the Examiner invited to contact the undersigned to arrange a mutually convenient time and manner therefor.

Respectfully submitted,  
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454313-2340.2**VERSION WITH MARKINGS TO SHOW CHANGES MADE****In the Claims:**

1. (Four Times Amended) A composition for reducing viral load of porcine circovirus-2 (PCV-2) in a pig comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 ORF1, a PCV-2 ORF2, or a PCV-2 ORF1 and ORF2[polypeptide].
2. (Four Time Amended) The[A] composition [for reducing viral load] of claim 1, wherein the vector contains and expresses PCV-2 ORF1 and ORF2[comprising a pharmaceutically or veterinarily or medically acceptable carrier and an active agent comprising a vector containing and expressing an exogenous nucleotide sequence, wherein the nucleotide sequence encodes a PCV-2 antigen].
17. (Twice Amended) The composition of claim[s] 1[ or 2], wherein the vector comprises a DNA vector plasmid, an E. coli cell, a baculovirus, a pig herpes virus[es], including Aujeszky's disease virus, a porcine adenovirus, or a poxvirus, including a vaccinia virus, an avipox virus, a canarypox virus, or a swinepox virus.
21. (Thrice Amended) The composition of claim[s] 1[ or 2], additionally including at least one immunogen from at least one additional pig pathogen, or a vector expressing such an immunogen, wherein the vector expressing the[, the at least one] immunogen [from at least one additional pig pathogen] can also be the vector expressing the PCV-2 ORF[polypeptide or antigen].
24. (Thrice amended) The composition of claim[s] 1[ or 2], wherein the vector contains and expresses [an] PCV-2 ORF1[ selected from the group consisting of ORFs 1 to 13 of a PCV-2 strain].
25. (Twice Amended) The composition of claim 1[7], wherein the vector contains and expresses [an] PCV-2 ORF2[ selected from the group consisting of ORFs 1 to 13 of a PCV-2 strain].
43. (Twice Amended) The method of claims 31, [or] 32, 54 or 55, wherein the composition additionally includes at least one immunogen from at least one additional pig pathogen or a vector expressing such an immunogen.
47. (Twice Amended) The method of claims 31, [or] 32, 54 or 55, wherein the vector comprises [a DNA vector plasmid,] an E. coli cell, a baculovirus, a pig herpes virus[es],

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[including] Aujeszky's disease virus, a porcine adenovirus, or a poxvirus[, including a vaccinia virus, an avipox virus, a canarypox virus, or a swinepox virus].

50. (Thrice Amended) The method of claim 31, additionally including at least one immunogen from at least one additional pig pathogen, or a vector expressing such an immunogen, wherein the vector expressing the[, the at least one] immunogen [from at least one additional pig pathogen] can also be the vector expressing the PCV-2 ORF[polypeptide or antigen].

54. (Thrice Amended) A[The] method of reducing viral load of PCV-2 in a pig comprising inducing an immunological or immunogenic response again PCV-2 in the pig comprising administering to the pig the composition of claim 24[claims 31 or 32, wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13 of a PCV-2 strain].

55. (Thrice Amended) A[The] method of reducing viral load of PCV-2 in a pig comprising inducing an immunological or immunogenic response again PCV-2 in the pig comprising administering to the pig the composition of claim 25[claim 47, wherein the vector contains and expresses an ORF selected from the group consisting of ORFs 1 to 13 of a PCV-2 strain].

62. (Twice Amended) The method of claims 31, [or] 32, 54 or 55, wherein the administering is prior to breeding.

63. (Twice Amended) The method of claims 31, [or] 32, 54 or 55, wherein the pig is a pregnant female pig.